

**Notice of Allowability**

Application No.

10/717,171

Examiner

Ernst V. Arnold

Applicant(s)

CONSTANTZ ET AL.

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/21/06.
2. ☒ The allowed claim(s) is/are 1-3, 6, 8, and 10-28 [renumbered as 1-24].
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance

  
JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
GROUP 1600

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brett Field on 01/09/07.

**Please amend the claims as follows:**

Claim 1 has been deleted and replaced with --- A method of producing a flowable composition that sets into a calcium phosphate containing product, said method comprising combining:

- (a) a water soluble silicate setting fluid;
  - (b) dry reactants comprising a calcium source and a phosphate source; and
  - (c) an osteoclastogenic agent which is a RANK ligand,
- in a ratio of (a) to (b) sufficient to produce said flowable composition that goes from a non-solid state to solid calcium phosphate containing product after setting. ---

Claims 5 and 12 have been cancelled.

Claim 15 has been deleted and replaced with --- A method of producing a paste that sets into a calcium phosphate containing product, said method comprising

(a) combining:

- (i) a water soluble silicate setting fluid;
  - (ii) dry reactants comprising a calcium source and a phosphate source; and
  - (iii) an osteoclastogenic agent which is a RANK ligand,
- wherein said dry reactants, setting fluid and osteoclastogenic agent are combined in a ratio of said dry reactants to said setting fluid sufficient to provide for said paste; and
- (b) mixing said combined reactants and setting fluid for a sufficient period of time to produce a paste capable of setting into a calcium phosphate containing product. ---

Claims 18 and 20 have been cancelled.

Claim 23 has been deleted and replaced with --- A flowable composition that sets into a solid calcium phosphate containing product, wherein said composition is produced by the method of claim 1. ---

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Claim 25 has been deleted and replaced with --- A kit for use in preparing a flowable composition that sets in an in vivo fluid environment into a solid calcium phosphate product said kit comprising:

- (a) a water soluble silicate setting fluid;
- (b) dry reactants comprising a calcium source and a phosphate source; and
- (c) an osteoclastogenic agent which is a RANK ligand. ---

Claim 26 has been deleted and replaced with --- A packaged calcium phosphate cement, said packaged cement comprising: a tubular element separated into a first compartment and at least one additional compartment by a removable barrier; wherein

- (i) dry reactants comprising a source of calcium and phosphate present in said first compartment;
- (ii) a water soluble silicate setting fluid or components thereof present in said at least one additional compartment; and
- (iii) an osteoclastogenic agent which is a RANK ligand present in either said first compartment, said at least one additional compartment or in a second additional compartment. ---

Claims 29-34 have been cancelled.

The following is an examiner's statement of reasons for allowance: The closest prior art reference of Chow et al. (US 5,525,148) does not teach or suggest, alone or in combination, the instant method of preparing a calcium phosphate product with a ligand for RANK osteoclastogenic agent. Chow et al. teaches methods of preparing calcium phosphate cements with osteoinductive factors. Osteoinductive factors recruit osteoblasts while osteoclastogenic agents recruit osteoclasts. This teaches away from the instant invention, which requires an osteoclastogenic agent that is a ligand for RANK. It would not have been obvious for one of ordinary skill in the art to add an osteoclastogenic agent to the composition of Chow et al., which teaches away from the use of such agents.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Claims 1-3, 6, 8, and 10-28 [renumbered as 1-24] are allowed.

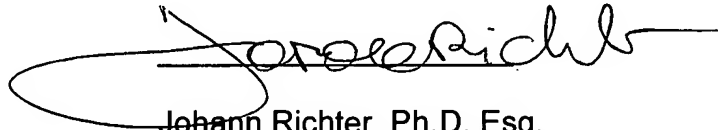
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold  
Patent Examiner  
Technology Center 1600  
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A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.  
Supervisory Patent Examiner  
Technology Center 1600